

Application No. 10/009,265
Art Unit 1615
Reply to Office Action of July 23, 2004

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1-19. Canceled

20. (NEW) A preparation for releasing a material selectively in a large intestine part of a lower gastrointestinal tract, comprising:

(1) an inner core comprising a material to be delivered to the large intestine;

(2) a disintegration layer surrounding said inner core, wherein said disintegration layer comprises a matrix comprising chitosan and particles of cystine dispersed in said matrix; and

(3) an enteric coating surrounding said disintegration layer.

21. (NEW) The preparation of claim 20, wherein the disintegration layer comprises cystine and chitosan in a ratio of 10/90 w/w to 90/10 W/W.

22. (NEW) The preparation of claim 20, wherein the preparation is a pharmaceutical composition and the material is an active-ingredient for therapeutic use.

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23. (NEW) The preparation of claim 20, wherein the disintegration layer is in the form of a capsule or a coating layer.

24. (NEW) The preparation of claim 20, wherein the inner core is in the form of a tablet or granule and the disintegration layer is in the form of a coating layer.

25. (NEW) The preparation of claim 20, wherein the matrix containing chitosan further comprises a substance that controls disintegration rate of the disintegration layer in the large intestine of the lower gastrointestinal tract.

26. (NEW) The preparation of claim 25, wherein the substance that controls the disintegration rate of the disintegration layer in the large intestine of the lower gastrointestinal tract is at least one substance selected from the group consisting of agar, pectin metal salt, carrageenin, gelatin, pectin, starch, cellulose, dimethylaminoethyl methacrylate/methylmethacrylate/butylmethacrylate copolymer and polyvinylacetal diethylaminoacetate.

27. (NEW) A formed product suitable for delivery of an active-ingredient for therapeutic use, comprising a matrix comprising chitosan and particles of cystine dispersed in said matrix.

28. (NEW) The formed product of claim 27, wherein cystine and chitosan are present in a ratio of 10/90 w/w to 90/10 W/W.

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29. (NEW) The formed product of claim 27, wherein the matrix further comprises at least one substance selected from the group consisting of agar, pectin metal salt, carrageenin, gelatin, pectin, starch, cellulose, dimethylaminoethyl methacrylate/methylmethacrylate/butylmethacrylate copolymer and polyvinylacetal diethylaminoacetate that controls disintegration rate of the formed product in the large intestine of the gastrointestinal tract.

30. (NEW) The formed product of claim 27, wherein the formed product is in the form of an empty hard capsule.

31. (NEW) The formed product of claim 27, wherein the formed product is in the form of a hard capsule containing an active-ingredient for therapeutic use.

32. (NEW) The formed product of claim 31, wherein the hard capsule further comprises an enteric coating on the outside of said hard capsule.

33. (NEW) The formed product of claim 30, 31 or 32, wherein the matrix containing chitosan further comprises at least one substance that controls disintegration rate in the large intestine of the lower gastrointestinal tract.

34. (NEW) The formed product of claim 33, wherein the at least one substance that controls the disintegration rate in the large intestine of the lower gastrointestinal tract is at least one

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substance selected from the group consisting of, agar, pectin metal salt, carrageenin, gelatin, pectin, starch, cellulose, dimethylaminoethyl methacrylate/methylmethacrylate/butylmethacrylate copolymer and polyvinylacetal diethylaminoacetate.

35. (NEW) A method for delivering a material to a large intestine part of a lower gastrointestinal tract of a patient, comprising the step of:

orally administering the formed product of claim 32 to a patient.

36. (NEW) A method for delivering a material selectively to a large intestine part of a lower gastrointestinal tract, comprising the steps of:

(a) orally administering the preparation according to claim 20 to a patient;

(b) dissolving the enteric polymer film in the small intestine;

(c) forming microfine holes in the matrix where particles of cystine are present; and

(d) disintegrating the matrix to selectively release the material in the large intestine.